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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,638	12/14/2000	Olivier De La Charriere	016800-429	6191

7590 03/20/2007
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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/735,638	DE LA CHARRIERE ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26, 28-50, 53, 54 and 121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-50, 53-54 and 121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 12-18-06 is acknowledged.

Claims included in the prosecution are 26, 28-50, 53-54 and 121.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26, 28, 32-34, 45-46 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.

Instant claims are drawn to a method of treatment of a sensitive skin wherein substance P has already been released due to the exposure to and contact with one substance P release active agent.

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20,

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pages 12-14 and claims). Since WO teaches the application of a substance P antagonist and since the function of an antagonist is to nullify the action of the agent against which it has the antagonist action, the reference reads on instant claims.

Applicant's extensive arguments and the declaration submitted have been fully considered, but are not found to be persuasive. Applicant argues that WO is directed to an allergic condition and it does not disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin of an individual in need of such treatment, where in the sensitive skin has an amount of substance P already released therein. Applicant further argues that WO relates to the use of piperidine derivatives, showing substance P antagonistic activity, for analgesic or anti-inflammatory properties in the treatment of pathological disorders. Applicant argues based on the declaration submitted that sensitive skin different from allergic skin and that the treatment of pathological disorder showing inflammatory conditions is not sufficient to anticipate or render obvious the claimed methods directed to treating the non-pathological condition of sensitive skin. These arguments are not persuasive since there is only one issue here: whether the reference teaches the release of substance P from skin and whether the antagonist of substance P would counteract the **'already released'** substance P. Since WO teaches skin disorders such as psoriasis, pruritis and sunburn on page 5, lines 19-20 besides the inflammatory conditions and allergic conditions which implies that the substance P is already released from the skin and since the antagonists taught by WO are substance P antagonists, counteracting the released substance P by the antagonists is inherent or implicit in WO. . According to instant claims, the symptoms

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include discomfort, prickly and erythema. As pointed out before, this means that the substance P is already released in the diseases taught by WO since without such release of substance P, the disease conditions would have manifested. Applicant has not shown that the skin conditions taught by WO do not include the diseases manifested by sensitive skin.

Claim Rejections - 35 U.S.C. § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 26, 28-50, 53-54, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions can be in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin wherein the substance P is already released. However, based on the teachings of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the

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substance P. Furthermore, since the function of a substance P antagonist is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the already released substance P. The examiner has already addressed this issue above. Applicant further argues that the rejection over WO 084 does not give full consideration to all of the claim elements and that patentable weight must be given to "having such amount of substance P already released therein, " and "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P". These arguments are not persuasive. With regard to the first point, that is, "having such amount of substance P already released therein, as already pointed out above, the disease conditions would not have manifested in a subject if the substance P has not been released. With regard to the second issue, that is, "by exposure to and contact with at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P", the examiner points out that WO teaches the application of substance P antagonist to the skin of the subjects who show these conditions and it would have been obvious to one of ordinary skill in the art that the amount of a therapeutic agent would depend upon the conditions of the manifested conditions. Since the severity of the condition depends upon the

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released substance P, it would have been obvious to one of ordinary skill in the art that the therapeutic amounts taught by WO would be proportional to the substance P released. Finally, the examiner points out that the function of a substance P antagonist is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state. Applicant's arguments that WO relates to the antagonizing binding or interaction of substance P with NK2 receptors and that the NK2 receptors are found in the smooth muscle not in the skin are not persuasive since as recognized by applicants themselves the compounds disclosed by WO have substance P antagonist activity and instant claims do not exclude those antagonists taught by WO. Applicant's arguments that the study (in the declaration) demonstrates that skin reactivity to lactic acid on the same group of individuals in the same study allowed applicant's to differentiate between people with sensitive skin and those with non-sensitive skin are not persuasive since applicants have not established that the skin taught by WO does not include sensitive skin.

5. Claims 26, 28-50, 53-54, 116 and 121 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252, WO 93/14084 individually or in combination (all are of record).

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Wallengren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallengren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note abstract the entire article).

The teachings of WO 93 have been discussed above.

The WO 83 discloses the use of a peptide substance P antagonist in medicinal preparations including topical formulations (abstract, page 8 and claims).

In essence, these references teach implicitly that substance P has already been released in the host skin. It would thus, be obvious to one of ordinary skill in the art that application of an antagonist to already released substance P to nullify its effect.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant, based on the declaration submitted argues that both the Wallengren articles relate to an allergic skin condition such as contact dermatitis or irritant delayed reaction. These arguments are not persuasive since as pointed out above, the function of a substance P antagonist is to antagonize the action of released substance P and nullify its effects and it would have been obvious to one of ordinary skill in the art at the time the invention was made that it would nullify the effects of substance P irrespective of whether the substance P is released from a sensitive skin or allergic skin or skin in a inflammatory state. Furthermore, as pointed out in the previous action, instant claims recite even discomfort as one of the symptoms and applicant has

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not shown that the discomfort is not overcome by the treatment of substance P antagonist in the prior art.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK